REMARKS

Issues Raised in the Office Action

Claims 1-6, 26-39 and 56-95 are currently pending in the application. In the Office Action dated November 13, 2003, claims 1-6, 26-39 and 56-95 were rejected. In this Paper the Applicant: cancels claims 2, 30, 31, 37, 39, 57, 67, 77, and 87; and amends existing claims 1, 3-6, 26, 33-35, 36, 38, 56, 58-61, 66, 68-71, 76, 78-81, 86, and 88-91.

Independent claims 1, 26, 36, 38, 56, 66, 76 and 86 have been amended to recite that the identified device or structure is placed within a housing for holding the device and structure, and a treatment is applied to the housing after the device or structure is within the housing, said "treatment comprising an effective quantity of an agent for disabling DNA from interfering with subsequent specimen's specific DNA analysis."

The Examiner has cited numerous examples of the use of various agents for sterilization (microbe killing quantities of an agent to render an object or surface biologically inactive). The present invention and claims, however, are directed to a device that has been treated with merely "an effective quantity of an agent for disabling DNA." The object of the use of this limited quantity of the DNA disabling agent is to prevent any DNA that becomes adhered to the outer surfaces of the probe container or the housing "from interfering with subsequent specimen's specific DNA analysis." The claimed "effective quantity of an agent for disabling DNA" is distinctly different from the amount of the agent used to perform microbial sterilization.

The Examiner cited Use of γ Irradiation to Eliminate DNA Contamination for PCR, *Deragon, Jean-Marc et al., Nucleic Acids Research, Vol. 18, No. 20, pp 6149.* This article identifies a similar problem confronted by the Applicant. In Deragon the problem was

contamination of the reagents or reaction mixture used for polymerase chain reaction (PCR) with small amounts of extraneous DNA. As the author points out, the inclusion of the extraneous DNA provides a second DNA source which also is reproduced in the PCR reaction. This presence of multiple DNA sources in the reaction mixture leads to confusion in the interpretation of the results.

The present inventor recognized this problem to be relevant to DNA kits that are assembled with individually purchased component parts (swabs, probes, wipes etc.). In such cases the individually purchased, and subsequently assembled, parts can become contaminated with the DNA from persons assembling the kits. It is a benefit to eliminate this extraneous DNA from the kit after assembly. It is, however, unnecessary to go the expense of re-sterilizing the entire kit.

As the Deragon paper sets forth, doses of radiation that are lower than those necessary to achieve "biological sterilization" can be used to prevent the extraneous DNA contained within the PCR reaction mixture from being amplified, and thus, confusing the interpretation of the results. Specifically, Deragon states that a dose of 150 krad eliminated amplification of 0.1 ng genomic DNA without affecting the PCR agents. In a second example, 200 krad of gamma radiation were sufficient to prevent copying of plasmid DNA even after 40 amplification cycles.

By contrast, Sterility Assurance Compliance-a Guide for Medical Device Manufacturers states, on page 7, that for gamma radiation, the recognized dose of radiation for the VD-Max method and the AAMI/ISO TIR 13409 method is an exposure of 25 kGy as the sterilization dose for products. Twenty-five kGy is equal to 2500 krads. Deragon supports that a much lower dose (150 krads – 200 krads) is sufficient to disable DNA from interfering with PCR. Thus, the

claimed "effective amount of an agent for disabling DNA from interfering with subsequent specimen's specific DNA analysis" is, in the case of gamma radiation, an amount that is approximately 1/10 of the amount of gamma radiation required for "bacterial sterilization."

The present invention, therefore, claims use of a much lower dose of radiation than is required to accomplish "biological sterilization" as set forth in *Sterility Assurance Compliance – A Guide for Medical Device Manufacturers.* The quantity of radiation claimed for disabling DNA in the present independent claims would be insufficient by any standard presented in the cited references to accomplish "biological sterilization." Therefore, the Applicant believes that the present claims distinguish over the cited prior art by claiming an "effective quantity of an agent for disabling DNA" which is far lower than the amounts required in the cited references to accomplish "biological sterilization."

The examiner cites Deragon in combination with other references that teach the use of sterilization. It is correct that it is desirable to have a DNA collection device sterile. However, none of the references teach exposure of a DNA collection device with "an effective quantity of an agent for disabling DNA from interfering with subsequent specimen specific DNA analysis applied to a housing after said housing contains said [device or substrate]. The cited references teach the use of a 10 fold greater amount of a reagent with the intent of accomplishing "biological sterilization." In the case in which multiple devices are assembled into a kit it is a benefit to avoid the unnecessary expense and time required to perform the greater exposure levels.

Amended independent claims 1, 26, 36, 38, 56, 66, 76, and 86 now specifically claim such a limited dosing of a housing containing a device for DNA collection with the phrase

"comprising an effective amount of an agent for disabling DNA from interfering with subsequent specimen's specific DNA analysis." The amount of agent necessary to disable DNA is less than the amount required to perform "biological sterilization" as is taught by the references cited by the Examiner.

Therefore, as the Applicant is claiming a treatment which comprises an effective quantity of an agent for disabling DNA rather than claiming an effective quantity of an agent for accomplishing "biological sterilization," the Applicant believes that the independent claims as now amended are allowable over the prior art cited by the Examiner, and that the case should be passed to issue.

Reconsideration of the application as amended respectfully is requested. The foregoing amendment and remarks are believed to be responsive to every matter raised in the office action. However, if some matter has been overlooked, an opportunity to correct the oversight would be appreciated.

Respectfully submitted,

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